



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/784,336	02/23/2004	Glen E. Jorgensen	47168-00158USD1	8712
30223	7590	07/05/2006	EXAMINER	
JENKENS & GILCHRIST, P.C. 225 WEST WASHINGTON SUITE 2600 CHICAGO, IL 60606			BIANCO, PATRICIA	
			ART UNIT	PAPER NUMBER
			3761	

DATE MAILED: 07/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	10/784,336		JORGENSEN ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Patricia M. Bianco		3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 February 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 4,5 and 8-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 4,5,8-10 and 12 is/are rejected.
- 7) ☒ Claim(s) 11 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>2/23/04</u> .   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Preliminary Amendment***

The preliminary amendment filed cancelled claims 1-3, 6 & 7, amended claim 4, and added claims 8-12. As a result, claims 4, 5, & 8-12 are currently pending.

### ***Specification***

Applicant has indicated co-pending applications in the first paragraph of the specification. The first page of the specification should be updated to clarify the status of all related applications noted in the first paragraph of the specification. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No. \_\_\_\_\_" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 4, 5, 8-10, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over McEwen et al. (4,828,716) in view of Kelly et al. (6,074,883). McEwen discloses a method wherein blood is collected from a patient using a needle set and collected or transferred into a container and tubing is connected to the container for delivery and withdrawal of components. The container has a piston (closure 16) that moves as a result of the centrifugation to separate the blood into its components. The container is placed within a centrifuge for a spin to separate the blood into its components. McEwen teaches that the separated serum is removed or withdrawn after

separating and is decanted (i.e. is expelled into a waste container). See figures 1a-1g; col. 7, line 28 to col. 9, line 49. McEwen also teaches that the components may be further separated by centrifugation until desired separation of components is achieved. Col. 14, lines 43-51.

McEwen discloses the invention substantially as claimed, however, fails to disclose specifically the following: that the separated red blood cells are expelled is into a waste bag; the step of attaching a hollow plunger rod with a port to displace separated platelet-poor plasma by moving the plunger toward the first port; a “soft” and “heavy” spin ; or that the collection container contains a small amount of anti-coagulant.

Kelly discloses a method and apparatus for using a disposable blood tube holder wherein the apparatus includes a hollow plunger rod with a port to separate components. The device of Kelly include a container that includes a connection means to attach a plunger (102) that has a hollow plunger rod (118) for removing separated components. At the time of the invention, it would have been obvious to one of ordinary skill in the art to have modified the apparatus of McEwen to include a hollow plunger rod to easily remove separated plasma without disturbing the separated cells in the container.

With respect to claim 12, it would have been obvious step to one having ordinary skill in the art to include an anti-coagulant in the container since it is standard operating procedure in blood collection. With respect to claims 8 and 9, McEwen teaches that the centrifuge has a motor and control device that can control the speed as desired. Therefore, a “soft” and “heavy” spin may be achieved by the method of McEwen. Since

Art Unit: 3761

McEwen teaches that separated serum is removed or withdrawn after separating and is decanted (i.e. is expelled into a waste container) it would be an obvious step in such a method to choose to decant separated red blood cells into a bag to one having ordinary skill in the art. If red blood cells are not the desired end product of the method, there would be no reason to keep them and decanting or expelling them into a waste container is standard operating procedure in medical laboratories. With respect to using a waste bag, a container is an equivalent to a bag.

***Allowable Subject Matter***

Claim 11 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The subject matter not found was the step of displacing red blood cells, platelet-rich plasma, and platelet-poor plasma automatically in a centrifuge that facilitates opening the ports in combination with the other elements (or steps) in the claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia M. Bianco whose telephone number is (571) 272-4940. The examiner can normally be reached on Monday to Friday 9:00-6:30, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone

Art Unit: 3761

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

June 26<sup>th</sup>, 2006

Patricia M Bianco  
Primary Examiner  
Art Unit 3761



**PATRICIA BIANCO  
PRIMARY EXAMINER**